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EXAMINER	
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ART UNIT	PAPER NUMBER
1652	

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/647,780	OUIMET ET AL.	
	Examin r	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE f this communication appears on the cover sh et with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *7-10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence alignement* .

The response filed on Sep. 26, 2002 as paper No. 15 is acknowledged. Claims 1-14 are pending in the application. Claims 1-6, 11, 13 and 14, in part concerning SEQ ID NO: 4 a novel human membrane protease, are the subject of this office action. Claims 1-6, 11, 13 and 14, in part concerning SEQ ID NO: 2, as well as claims 7-10 and 12 are withdrawn from the consideration as directed to the non-elected invention.

DETAILED ACTION

1. Election/Restriction

Applicant's election with traverse of Group VI, claims 1-6, 11, 13, and 14 in part concerning the human novel membrane protease of SEQ ID NO: 4, is acknowledged. The traversal is on the ground(s) that " the actual PCT Examiners did not restrict this case and held to the contrary that there was no lack of unity of invention."

This is not found persuasive because the examiner of the national stage application is not bound to the opinions of the IPER examiner.

Furthermore, the Applicants argue, "claims are based on the general inventive concept of identifying a new Metalloprotease called NEP II."

Applicants' argument has been fully considered, but is found not persuasive for the following reason. "The concept of identifying" is not a special technical feature that unifies the invention. It's the concept reduced to practice, i.e. a specific protein identified by its own chemical structure is a special technical feature. The claims in the current application are directed to two NEP II having different chemical structures and

originating from different species. Therefore, unity of invention is lacking despite of the fact that both amino acid sequences are contribution over the prior art.

The requirement of restriction is still deemed proper and is therefore made FINAL.

2. Objection

The specification is objected to for a vague definition of the term "biologically active". On page 2, line 13, Applicants write: "biologically active, i.e. they have biological properties identical or similar of the biological properties of the NEP II polypeptide of SEQ ID NO. 2 or SEQ ID NO. 4, namely metalloprotease activity."

The term "similar" is a relative term, which renders the definition of the term "biologically active" indefinite. One of ordinary skill in the art would not be reasonably apprised of the scope of the term. It is unclear how similar the activity should be to be within the scope of the term "metalloprotease activity". In addition, the term "metalloprotease activity" itself has a very broad meaning, because there is a large number of metalloproteases. Therefore, it is not known which metalloprotease activity Applicants mean, especially that any metalloprotease activity of SEQ ID NO: 4, or SEQ ID NO: 2, is disclosed in the application.

The specification is objected to for incorrect writing of the abbreviation of the term "sequence identification number." Applicants use the abbreviation SEQ ID No. 4, whereas the correct writing is SEQ ID NO: 4.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. Rejections

3.1. 35 USC section 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-6, 11, 13, and 14 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The Applicants disclose the novel human protein encoded by DNA molecule of SEQ ID NO: 3, and having amino acid sequences described by SEQ ID NO: 4, named NEP II. The sequence analysis indicates that the claimed protein contains a site responsible for binding the zinc, the HEITH sequence (amino acid 2-6 of the sequence SEQ ID NO. 4), which led Applicants to classify it as the protein belonging to the metalloprotease family. As a support for this notion Applicants also teach, page 12, line 32, that human NEP II is in 82% homologous to rat NEP II (SEQ ID NO: 2), which in turn is in 52%, 40% and 28% homologous to the NEP I, ECE and Kell enzymes (metalloproteases), known in the art. Thus, the asserted function of NEP II is to be a novel human membrane–bound metalloprotease. Those skilled in the art know that annotation of function on the basis of homology to the protein with a well established biologic function is in many cases erroneous; a good example is

presented by Seffernick and her co-workers, who teach that melamine deaminase and atrazine chlorohydrolase are 98% identical but functionally different; copy encolosed.

Applicants do not describe any functional characteristics of the polypeptide of SEQ ID NO: 4. The substrate for the assumed enzymatic activity is not disclosed and specification fails to teach any assay, and its results, providing evidence that the NEPII protein has the metalloprotease activity. Thus, although Applicants assert the SEQ ID NO: 4 is a novel human metalloprotease, its biologic role and its significance are not disclosed.

Applicants assert the protein of SEQ ID NO: 4 can be used to screen for inhibitors of its activity. However, because either the activity or the substrates are disclosed, the screening for inhibitors is not possible.

Applicants offer to treat disorders involving the peptide transmissions in which NEP II participates. However, Applicants do not disclose any particular disorder in which the production of the protein of SEQ ID NO: 4 was shown to be insufficient or excessive, or the protein produced defective. Therefore, this use is theoretical and not specific. In conclusion, these utilities cannot be considered to be specific and substantial because Applicants fails to teach any specific biochemical reaction that polypeptide of SEQ ID NO: 4 is involved in, as well as any specific relationship of this reaction to any disease. Thus, specification fails to disclose any particular activity or biological significance for the polypeptide of SEQ ID NO: 4, which is said to have a potential function based upon its amino acid sequence containing the zinc binding site and a week homology to above mentioned metalloproteases.

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Applicants have failed to establish any function or specific and substantial utility for the polypeptide of SEQ ID NO: 4, because the polypeptide is not disclosed to have any biologic activity.

It appears that, at present, the main utility of the polypeptide is to carry out further research to identify its specific biological function, i.e., any function envisioned by Applicants. Utilities that require carrying out further research to identify or reasonably confirm a real world use do not have a substantial utility.

Although a specific and substantial credible utility might be found for the claimed isolated composition, after further research, this further characterization is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. Thus, there has been no immediately apparent or "real world" utility identified as of the filling date of the instant application.

Applicant is referred to the revised guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-6, 11 13 and 14 are also rejected under 35 USC § 112, the first paragraph. Since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention, so that it would operate as intended, without undue experimentation.

Claim 6 is rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter. The claim is directed to polyclonal antibodies that are capable of recognizing specifically a sequence comprising a sequence derived or homologous to SEQ ID NO: 4. As discussed bellow in rejection under 35 USC section 102, the amino acid sequence of CALLA, a common acute lymphoblastic leukemia antigen comprises a sequence derived or homologous to SEQ ID NO: 4.

Polyclonal antibodies against CALLA are present in blood of large numbers of patients suffering from lymphoblastic leukemia, and as such are product of nature. Thus, claim 6 is rejected as directed to the product of nature.

3.2. 35 USC section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 6, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the following terms that render the claims indefinite:

1) a sequence derived from the sequence of SEQ ID NO: 4 or 3,

2) a sequence homologous to the sequence of SEQ ID NO: 4 or 3,

3) a biologically active fragment of SEQ ID NO: 4.

Regarding term 1), on page 3 line 6 Applicants write, "The term 'derived' polypeptide is intended to mean any polypeptide resulting from a modification of genetic

and/or chemical type of the sequence SEQ ID No. 2 or SEQ ID No. 4, i.e. by mutation, deletion, addition, substitution and/or chemical modification of at least one amino acid, or any isoform having a sequence identical to the sequence SEQ ID No. 2 or SEQ ID No. 4, but containing at least one amino acid in the D form."

The above definition of the "sequence derived" encompasses all polypeptides originating from any natural and man-made sources, because every polypeptide can be made from another polypeptide by mutation, addition, substitution and chemical modification of at least one amino acid. Therefore, because of the extremely large scope the term "sequence derived" is indefinite.

With respect to term 2), on page 2, line 27, Applicants write, "The term 'homologous' polypeptide is intended to mean more particularly any peptide which can be isolated from mammalian species other than rats or humans."

The scope of the term is extremely large because of the extremely large number of mammal species known and unknown to those skilled in the art. In addition, the term "homologous" is indefinite when used without simultaneous quantification. A polypeptide is homologous to a second polypeptide in 99.9%, but another polypeptide is homologous to said second polypeptide in 0.1%. However, in both cases the term "homologous" is used.

The term "biologically active" is defined on page 3, line 13, where Applicants write: "Said polypeptides derived from or homologous to, or the polypeptide fragments of, the polypeptide of sequence SEQ ID NO. 2 or SEQ ID NO. 4 are biologically active,

i.e. they have biological properties identical or similar of the biological properties of the NEP II polypeptide of SEQ ID NO. 2 or SEQ ID NO. 4, namely metalloprotease activity."

The term "similar" is a relative term, which renders the definition of the term "biologically active" indefinite. One of ordinary skill in the art would not be reasonably apprised of the scope of the term. It is unclear how similar the activity should be to be within the scope of the term "metalloprotease activity". In addition, the term "metaloprotease activity" itself has a very broad meaning, because there is a large number of metalloproteases. Therefore, it is not known which metalloprotease activity applicants mean, especially that no specific metalloprotease activities of SEQ ID NO: 4, or SEQ ID NO: 2, are disclosed in the application.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the term "hybridize specifically" that renders the claims indefinite. The examiner acknowledges exemplifying hybridization conditions in the specification (page 4), however it is not clear which conditions are to be used to select a sequence that "hybridize specifically" with SEQ ID NO: 3, i.e. which hybridization conditions are included and excluded from the scope of the claim. There are many sets of hybridzation conditions in the prior art that are used for hybridization assays. The result of the hybridization experiment would vary in dependence of experimentator and laboratory. Specifying the hybridization conditions in the claims will ablate this rejection.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The claim is directed to monoclonal antibodies, polyclonal antibodies and their fragments, chimeric antibodies and immunoconjugates that are capable of recognizing specifically a polypeptide of claim 1. In addition, the polypeptides of claim 1 present a large number of antigens further contributing to the indefinitness of the claim.

Assuming that SEQ ID NO: 4 identifies a metalloprotease the following rejection is proper. Claim 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps and essential elements such omission amounting to a gap between the steps and elements. See MPEP § 2172.01. The omitted steps and elements underlined & written in bold, are:

1. contacting the protein of SEQ ID NO: 4 with its **substrate** in the control sample,
2. contacting the protein of SEQ ID NO: 4 with **its substrate** and the test compound in the test sample,
3. carrying out the protease reaction in both samples for a certain time,
4. measuring the concentration of the reaction product in control and test sample, and
5. evaluating the degree of inhibiton by calculating the difference in concentration of products in control and test sample, wherein the

difference of X% is a threshold for the inhibitory effect of the tested compound.

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substrate is unknown.

3.3. 35 USC section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.3.1. Lack of written description

Claims 1- 6, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **Amino acid sequence of SEQ ID NO: 4 consists of 116 amino acids, however its encoding SEQ ID NO: 3 consists of only 327 nucleotides. The nucleotide sequence encoding 116 amino acid should be 348 nucleotides long. SEQ ID NO: 3 encodes residues 1-109 of SEQ ID NO: 4. Thus, the last 7 amino acids of the C-terminal of claimed human polypeptide are missing their codons. As such, the actual sequence of the polypeptide of SEQ ID NO: 4 is unclear.**

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Assuming that SEQ ID NO: 4 identifies a metalloprotease the following rejection is proper.

Claim 1, 6, 11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, 6, 11 and 13-14 are rejected as directed to a large species of the polypeptides that comprise:

a) SEQ ID NO: 4,

b) a sequence derived from SEQ ID NO: 4,

c) a sequence homologous to SEQ ID NO: 4, and

d) a biologically active fragment of SEQ ID NO: 4.

The claims are directed to a large and variable genus of polypeptides. The specification discloses only a single species of the claimed genus, i.e., SEQ ID NO: 4, but the disclosure is silent about the function/structure relationship for SEQ ID NO: 4. The structure and function of the other species of the genus are not disclosed, including the species listed under d); see the above rejection for indefiniteness. The applicants have not provided information sufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filled.

Assuming that 1) SEQ ID NO: 4 identifies a metalloprotease, and 2) SEQ ID NO: 3 encodes SEQ ID NO: 4 the following rejection is proper.

Claims 2 - 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to the large and variable genus of DNA molecules that:

a) comprise SEQ ID NO: 3,

b) comprise a sequence derived from SEQ ID NO: 3

c) comprise a sequence that is homologous to SEQ ID NO: 3

d) comprise a nucleotide sequence complementary to that of a) –c).

The specification discloses only a single species of the claimed genus, i.e. SEQ ID NO: 3. The structure and function of the other species of the claimed genus are not disclosed. Therefore, the disclosure does not provide information sufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Thus, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filled.

3.3.2. Scope of enablement

Assuming that 1) SEQ ID NO: 4 identifies a metalloprotease, and 2) SEQ ID NO: 3 encodes SEQ ID NO: 4 the following rejection is proper.

Claims 1, 6, 11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide identified by SEQ ID NO: 4, does not reasonably provide enablement for all peptides that comprise

a) SEQ ID NO: 4,

b) a sequence derived from SEQ ID NO: 4,

c) A sequence homologous to SEQ ID NO: 4, and

d) a biologically active fragment of SEQ ID NO: 4.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The genus of polypeptides listed under a) – d) is a large and variable genus encompassing the species that do not have the desired functionality.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any polypeptide comprising

a) SEQ ID NO: 4,

b) a sequence derived from SEQ ID NO: 4,

c) a sequence homologous to SEQ ID NO: 4, and

d) a biologically active fragment of SEQ ID NO: 4.

The source of this polypeptide may be any living organism or a man-made source. While methods of gene cloning and manipulation are well known in the relevant art, and skills of the artisans highly developed, constructing this extremely large number of all possible DNA molecules encoding these polypeptides, expressing them, and checking enzymatic activity of expressed polypeptides is outside the realm of routine experimentation.

The disclosure does not set forth identifying characteristics of such polypeptides listed under b) - d). Applicants did not provide any guidance as to how to obtain a derivative sequences or how homologous the sequence should be to retain the desired activity. Even the obtaining the biologically active fragment is not enabled because the term, as used by Applicants is indefinite. Without further guidance on the part of Applicants the experimentation left to those skilled in the art is improperly extensive and undue.

Claims 2 - 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA identified by SEQ ID NO: 3, does not reasonably provide enablement for all the DNA molecules that

a) comprise SEQ ID NO: 3,

b) comprise a sequence derived from SEQ ID NO: 3

c) comprise a sequence that is homologous to SEQ ID NO: 3

d) comprise a nucleotide sequence complementary to that of a) –c).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The genus of DNA molecules that comprise molecules enumerated under a) - d) is a large and variable genus encompassing the species that do not encode the protein having the desired functionality.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any isolated nucleic acid molecule that

a) comprise SEQ ID NO: 3,

b) comprise a sequence derived from SEQ ID NO: 3

c) comprise a sequence that is homologous to SEQ ID NO: 3

d) comprise a nucleotide sequence complementary to that of a) –c).

The source of this molecule is any living organism or a man-made source. While methods of gene cloning and manipulation are well known in the relevant art, and skills of the artisans highly developed, constructing an extremely large number of all possible DNA molecules characterized under a)-d) is outside the realm of routine experimentation.

The disclosure does not set forth any identifying characteristics of the above listed DNA molecules. Applicants did not provide any guidance or examples how construct a DNA molecule that is a derivative of SEQ ID NO: 3, or how homologous the DNA sequence should be, so as to preserve the capacity of encoding the polypeptide with required functionality. Without that guidance the experimentation left to those skilled in the art is improperly extensive and undue.

3.4. 35 USC, 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Shipp et al. (Molecular cloning of the common acute lymphoblastic leukemia antigen (CALLA) identifies type II integral membrane protein, Proc. Natl. Acad. Sci. USA, 1988, 85, 4819-4823, copy enclosed).

Claim 1 is directed to a polypeptide comprising an amino acid sequence derived from or homologous to SEQ ID NO: 4.

Claim 2 is directed to a nucleic acid comprising a nucleotide sequence derived from or homologous to SEQ ID NO: 3.

Shipp et al. disclose, page 4821, Fig. 2, a protein called CALLA antigen containing in positions 583-696 the amino acid sequence homologous in 70.5% to amino acid residues 1-114 of SEQ ID NO: 4, including 15 amino acids identical to residues 1-15 of SEQ ID NO: 4; see the enclosed sequence alignment. Thus, Shipp et al. disclose polypeptide comprising an amino acid sequence derived from or homologous to SEQ ID NO: 4 as claimed in claim 1 of the instant application.

Shipp et al disclose, page 4821, Fig. 2, the DNA sequence encoding a protein called CALLA antigen containing in positions 1758- 2084 the nucleotide sequence derived from and homologous to nucleotide 1- 327 of SEQ ID NO: 3. Thus, Shipp et al. disclose polynucleotide comprising a sequence derived from or homologous to SEQ ID NO: 3. One skilled in the art concludes that Shipp et al. teach the nucleic acid claimed in claim 2.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Ritz et al. (A monoclonal antibody to human acute lymphoblastic leukaemia antigen, Nature 1980, 283, 583-585, copy enclosed) and Shipp et al, see above.

Claim 6 is directed to a monoclonal antibody obtained using a sequence comprising a sequence derived or homologous to SEQ ID NO: 4.

Ritz et al. teach production of monoclonal antibody against CALLA, which as discusses above, is a polypeptide comprising an amino acid sequence derived from or homologous to SEQ ID NO: 3. In conclusion, Ritz et al teach the invention of claim 6.

4. Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

Art Unit 1652

PONNATHAPU ACHUTAMURTHY
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